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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/279,275	07/22/1994	HOWARD L. WEINER	101016104US1	7626

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/279,275	WEINER ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,31-33, 35, 37,38,40 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *29,31-33,35,37,38,40 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment, remarks, and terminal disclaimer, filed 12/31/03, have been entered.

2. Claims 29, 31-33, 35, 37-38, and 40, and newly added Claim 42, are pending and being acted upon.

3. In view of the Terminal Disclaimer, filed 12/31/03, the double patenting rejection of Claim 37 over Claims 1, 9, 14, 19, and 24 of U.S. Patent No. 5,869,054 and Claim 2 of U.S. Patent No. 6,036,957 has been withdrawn.

4. The amendment to the specification filed 12/31/03 is objected to for the following reason. A proper claim of priority should include the relationships of the instant application to the priority documents. Also, it is unclear precisely what one application being "based on" another application is intended to mean.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 29, 31-33, 35, 37-38, and 40, and newly added Claim 42, stand/are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

a method for the treatment of myelin basic protein (MBP) induced experimental allergic encephalomyelitis (EAE) in Lewis rats, and a method for the treatment of adjuvant induced arthritis (AA) in Lewis rats,

does not reasonably provide enablement for,

a method for the treatment of a T cell-mediated or T cell-dependent autoimmune disease by suppressing an autoimmune response associated with said disease in a human presenting with

said autoimmune response, said method comprising orally or enterally administering to said human at least one antigen in an amount effective to suppress said autoimmune response, said antigen selected from the group consisting of autoantigens specific for said autoimmune disease, said suppression comprising elicitation of suppressor T cells specific to said administered antigen, or

a method of treating a T cell-mediated or T cell-dependent autoimmune disease by suppressing an autoimmune response associated with said disease in a human presenting with said autoimmune response, said method comprising orally or enterally administering to said human at least one antigen in an amount effective to suppress said autoimmune response said antigen selected from the group consisting of autoantigens specific for said autoimmune disease, or

a method of suppressing an autoimmune response in a human presenting with said autoimmune response, said method comprising orally or enterally administering to said human at least one antigen in an amount effective to suppress said autoimmune response, said antigen selected from the group consisting of autoantigens specific for said autoimmune disease,

for the reasons of record as set forth in Paper No. 78, mailed 3/19/02, and maintained in the paper mailed 12/02/02.

Applicant's arguments, filed 12/31/03, have been fully considered but they are not persuasive. Applicant argues that "It is applicants' position that the specification of the present invention is enabling for methods of the presently claimed invention, which is not directed to a cure of autoimmune diseases, nor to treatment of an autoimmune disease as might have been defined by endpoints or differences from placebo in a clinical trial. Rather, both previously presented claims 29 and 35 and new claim 42 are limited to suppression of an autoimmune response."

The instant claims (other than new Claim 42) are drawn to a method of treatment or a method of treating. A review of the specification shows that "treatment" is defined as "both the prophylactic measures to prevent such autoimmune diseases and the suppression or alleviation of symptoms after the onset of such autoimmune diseases" (page 6). Accordingly, Applicant's new assertion regarding the nature of the claimed invention is not supported by the specification.

Applicant reviews the examples of the specification.

As set forth above, the specification is enabling for the methods set forth in the examples. It remains the Examiner's position that in the instant case, animal models are insufficient enablement for claims encompassing the treatment of human disease given the facts of record that demonstrate that the methods of the instant claims do not work in humans.

Applicant argues, "The Examiner has also commented directly to the inclusion of poison ivy in the specification. Applicants submit that if the Examiner would prefer, reference to "poison ivy" may be removed from the specification."

References to poison ivy may not be removed from the specification as this would necessitate a new matter objection.

Applicant argues "The clinical trials to which the Examiner refers did not measure autoimmune response but rather a group of macroscopic observational parameters. Moreover, one clinical trial for rheumatoid arthritis succeeded, see, Barnett et al., *Arthritis and Rheumatism* 1998, 41(2):290-297, of record."

Regarding the parameters measured in the trials, said parameters are encompassed by the specification's definition of treatment (see again page 6). Regarding the teachings of Barnett et al., said teachings further demonstrate the unpredictability of the claimed method in that only limited success was achieved with just a single dosage. Also note the conclusion of the Abstract, "Further controlled studies are required to assess the efficacy of this treatment approach." Clearly, some 10 years after the priority date of the instant application, the method of the instant claims was still considered to be unpredictable. Accordingly, Applicant's assertions as to the method of the instant claims being enabled in its breadth at the time of filing cannot be found convincing.

7. Claims 29, 31-33, 35, 37-38, and 40 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method for the treatment of a T cell-mediated or T cell-dependent autoimmune disease by suppressing an autoimmune response associated with said disease in a human presenting with said autoimmune response (Claims 29 and 35),

B) a method of treating MS comprising administering an autoantigen, wherein said autoantigen is bovine myelin basic protein (Claim 37).

Applicant's arguments, filed 12/31/03, have been fully considered but they are not persuasive. Applicant argues that the method of Claims 29 and 35 is supported at page 1, lines 24-26 of the specification.

A review of page 1, lines 24-26 reveals insufficient support for the claimed method. Indeed, it is unlikely that support for a claimed method would be found in the Background section of an application as said finding would most likely require a rejection over the prior art.

Applicant argues that, as set forth in MPEP 2164.02 "because only an enabling disclosure is required, applicant need not describe all embodiments."

Applicant is advised that MPEP 2164.02 considers rejections made for lack of enablement. The rejection in question has been made for the introduction of new matter into the claims.

Applicant argues that Examples 4 and 6, and the disclosure at pages 2, 7, and 8 provide adequate support for the method of Claim 37.

Applicant is advised that specific embodiments, e.g., Examples 4 and 6, seldom provide adequate support for generic claims. Thus, the fact that the specification discloses an EAE animal model in which disease is induced with specific fragments of bMBP, does not provide support for the more generic limitations of Claim 37.

8. The following are new grounds of rejection necessitated by Applicant's amendment.

9. Claim 42 is rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s)

had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) a method of suppressing an autoimmune response in a human presenting with said autoimmune response, said method comprising orally or enterally administering to said human at least one antigen in an amount effective to suppress said autoimmune response, said antigen selected from the group consisting of autoantigens specific for said autoimmune disease.

Applicant indicates that support for the claim can be found at page 6 of the specification. A review of the page reveals no support for the newly claimed limitations. For example, the specification discloses suppression of symptoms, but no "suppressing an autoimmune response" as claimed. As set forth previously, the specification also fails to support a method wherein a human "presents" with an autoimmune response.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

12. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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4/2/03
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